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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,376	07/29/2003	Michael P. Schrom	64862/PO66US/10502007	8953

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EXAMINER

BOCKELMAN, MARK

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/630,376

Applicant(s)

SCHROM ET AL.

Examiner

Mark W. Bockelman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16, 19-28 and 30-40 is/are pending in the application.
- 4a) Of the above claim(s) 1-10 and 34-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-16, 19-28, 30-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1-25-2005
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10-14, 16, 21-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Kordis et al. USPN 5,476,495.

Kordis shows an electrode catheter with spiral wound conductors in a mapping probe catheter 18 lead body that is implanted into the body during procedures of mapping and ablation. Figures 31 –33 show probe cross-section comprising member 96 of the mapping probe 18 having an inner portion 106 forming a lumen 108. An inner composite unitary layer comprising 106, 110, 114 is shown having at least one conductor 110 which is encapsulated by sublayer members 106 and 114. The device also has an outer layer 112 having at least one conductor 112. At least connector 44 communicates with a plethora of electrodes on the basket member 24. The mapping probe can be much smaller than 34 French (column 6 lines 46-50) and is made of materials Pebax and Teflon that can be used as extrusion materials.

Claims 10-14, 16, 21-26, 28, 30, 32- 33, are rejected under 35 U.S.C. 102(b) as being anticipated by Diaz USPN 5,824,026.

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Diaz teaches a catheter extending from the inner lumen to the wall 17, comprising a unitary composite layer of extrusion material including members 32, 34, 44 that provides a lumen and has a inner conductor member 34,42 encapsulated therein, as well as a second conductor 46 wound in an opposite direction from the first conductor and an outer layer 36, and at least one electrode (see stripped region 20) that is inherently connected to a stimulus for depolarizing the heart (namely a defibrillator –see column 6 lines 25-35) through some sort of connector (be it a welded connection or pin). The inner layer 34 and/or 42 may additionally be connected to the sensor electrodes 22, 24, 26 for a total of 6 electrodes. Polyurethane which is considered an extrusion material (i.e. material that can be used in extrusion) is used in the outer covering 17 and therefore the unitary wall is comprised of an extrusion material. For the defibrillator embodiment the catheter is sized well below a 34 french diameter – column 6 lines 32-35. Layer 34 and 46 are wound in opposite directions to layer 42.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10-16, 19-20, 22-28, 30-31, 33 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Brownlee

USPN 5,772,693 (alone or further in view of Kordis et al. USPN 5,476,495, Diaz USPN 5,824,026 or Crowley USPN 5,840,031).

Applicant's claims have multiple meanings regarding the coils being wound in opposite directions. As a first application of the art the examiner regards the language to be a product by process that is indistinguishable in the products. Thus, Brownlee 's various coil members could have been wound in opposite directions, I.e left to right for the first layer and right to left for the second layer. In this regard Brownlee further shows a catheter construction (see figure 20) with a unitary composite layer including the two inner most coils 56 and two inner most covering 54 to define a lumen with second most inner coil member 56 being encapsulated by the two polymer members. An outer coil member and outer covering provide for an encapsulated outer conductor. The catheter is formed with extrusion material on each of the coils followed by insertion and heat setting to achieve its shape. See column 5 lines 10-26 and column 12 lines 15-25 for instance. Connectors 12 and 14 are formed at the proximal end and in the embodiment of figure 13, 5 electrodes 22, 24, 80, 38 and 41 are shown. The device is connected to a pacemaker to provide a stimulus for pacing the heart.

Alternatively to have have position the coils so that the helix member are oriented in different clockwise and counter clockwise directions about the lumen would have been obvious in view of Kordis et al. USPN 5,476,495, Diaz USPN 5,824,026 or Crowley USPN 5,840,031 which demonstrate that providing such for providing enhanced catheter torque was well established in the art prior to applicant's invention.

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Claims 21 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brownlee USPN 5,772,693 in view of Kordis et al. USPN 5,476,495, Diaz USPN 5,824,026 .

. While Brownlee is silent to the cross-sectional size of the lead a size 34 french is very large and to have manufacture the Brownlee lead smaller than such would have been apparent to those of ordinary skill in the art. Kordis et al and Diaz show such catheters to be smaller than 34 french.

Claims 15, 19-20, 27, 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diaz USPN 5,824,026 or Kordis et al. USPN 5,476,495 alone or in further in view of Brownlee USPN 5,772,693 USPN 5,476,495. Applicant differs in reciting extrusion material in the second layer. It is believes that the wiring of Diaz and Kordis could be made by extrusion and therefor comprise extrusion material or otherwise, to have extruded the device so that outer layers and inner layer mesh would have been obvious in view of Brownlee.

Response to Arguments

Applicant's arguments filed April 6, 2005 have been fully considered but they are not persuasive. Applicant argues that none of the references teach a unitary layer with a coil encapsulated therein to form an inner lumen. The examiner notes that unitary only means forming a unit and thus the interpretation of the references showing a composite layer of a coil between two polymer sheaths may be considered to be a composite

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unitary layer with a coil member encapsulated therein. Therefore applicant's arguments are not deemed persuasive. Applicant instead appears to be arguing that the coil member is completely embedded within the inner layer of a single material which is not what is being claimed at this time.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark W. Bockelman whose telephone number is (571) 272-4941. The examiner can normally be reached on Monday - Friday 8:00 to 4:30.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272 -4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MWB

June 25, 2005


MARK BOCKELMAN
PRIMARY EXAMINER